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13. ABSTRACT (Maximum 200 words)

This study is determining the incidence and impact of PMS and Dysmenorrhea on female soldiers' job performance and cognitive processing before and after biofeedback therapy. The incidence survey found that 55 % of female soldiers experienced PMS, dysmenorrhea, or a combination of both. Forty-one percent of these soldiers reported significant PMS, 17 % reported significant dysmenorrhea and 42 % reported a combination of both. Each filled out a month-long log of their symptoms and their effect on work performance before and after six weeks of EMG and temperature biofeedback combined with muscle tension awareness and relaxation training. The Automated Neuropsychological Assessment Metrics evaluation (ANAM) was given to twenty-one soldiers at the lowest and then at the highest symptom level to measure the relationship between cognitive functioning and menstrual cycle related symptoms. The tests showed that women's cognitive functioning is not effected by PMS or dysmenorrhea. To date, five participants have taken a post-treatment ANAM test at their highest symptom level to determine the effects of treatment on cognitive functioning. Eight participants have completed the treatment phase and seventeen are still in progress. The results from the completed subjects showed that their symptoms decreased in intensity and frequency.

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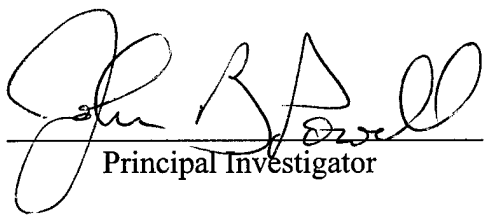

22 April, 1996

Principal Investigator

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1. INTRODUCTION:

a. **Objectives**:

(1) To determine whether Premenstrual Syndrome (PMS) and dysmenorrhea have a significant impact on the job performance of female soldiers who request treatment for these problems.

(2) To determine whether PMS and dysmenorrhea have a significant impact on the cognitive functioning of female soldiers who request treatment for these problems and if this impact correlates highly with changes in work performance.

(3) To determine whether biofeedback intervention will make a significant impact on the work performance of female soldiers requesting treatment for PMS or dysmenorrhea by producing about a 50% reduction in pain (a combination of frequency, intensity, and duration) among about 80 percent of those requesting treatment.

(4) To determine whether female soldiers given biofeedback training for PMS and dysmenorrhea who do not successfully complete their training (do not learn the tasks) will not show a change in the intensity of their symptoms from before to after training.

b. **Hypotheses**:

(1) That PMS and dysmenorrhea have a significant impact on the job performance of female soldiers who request treatment for these problems. Significant is defined as sufficient impact to alter the performance rating on the equivalent of an ARTEP.

(2) That PMS and dysmenorrhea have a significant impact on the cognitive functioning of female soldiers who request treatment for these problems and that this impact correlates highly with changes in work performance.

(3) That biofeedback intervention will have a significant impact on the work performance of female soldiers requesting treatment for PMS or dysmenorrhea by producing about a 50% reduction in pain (a combination of frequency, intensity, and duration) among about 80 percent of those requesting treatment.

(4) That female soldiers given biofeedback training for PMS and dysmenorrhea who do not successfully complete their training (do not learn the tasks) will not show a change in the intensity of their symptoms from before to after training.

c. **Medical and military applications**:

(1) Medical Significance: PMS and dysmenorrhea have a significant impact on the ability of many women to work consistently. This study is a direct effort to assess the impact of PMS and dysmenorrhea upon the ability of female soldiers requesting treatment for these problems on their work performance and the ability of a well recognized treatment to ameliorate that impact.

(2) Military Significance: There is no reason to think that the impact of PMS and dysmenorrhea on female soldiers is different from that of their civilian counterparts. Thus, it is very likely that significant numbers of female soldiers lose significant work and work less effectively than they should do to PMS and dysmenorrhea. Determination of the impact of these problems on job performance of female soldiers desiring treatment is important to understanding the impact of these problems on the military in general. Determination of whether a short, inexpensive intervention can significantly ameliorate the impact on job performance is equally important.

d. **Status**:

(1) Overview: PMS is an overlapping group of uncomfortable to debilitating

symptoms which tend to begin seven to ten days before menstruation and end a few hours after the onset of menstruation. Primary dysmenorrhea can also be debilitating and tends to begin just prior to the onset of or during menstruation. Sometimes it stops shortly after menstruation begins and sometimes it continues through the entire menstrual phase. Thus, there tends to be some overlap in the timing of the two problems and the same women can have both. About fifty percent (range of 30 to 87 percent) of young adult women report significant symptoms of PMS and about thirty percent report significant dysmenorrhea. Between two and seventeen percent of women have PMS so severe that they are debilitated for part of the month. Up to about thirty percent of women report severe symptoms of dysmenorrhea for at least one day per month and at least six percent are disabled for a day or more per month. No studies on either PMS or dysmenorrhea among soldiers were located so there is no information available about the actual impact of these disorders on female soldiers' job performance.

A number of studies have shown that biofeedback can effectively reduce the intensity of the symptoms of both primary PMS and dysmenorrhea. Biofeedback is commonly used in military settings for the treatment of headache and anxiety but not widely for either PMS or dysmenorrhea. It is hypothesized that those soldiers who learn their biofeedback tasks successfully will show decreased symptom activity and increased job performance while those who do not learn will not show a change in performance.

(2) Incidence, impact, and request for treatment of PMS and dysmenorrhea in the general and military populations: PMS is an overlapping group of symptoms which tend to begin seven to ten days before menstruation and end a few hours after the onset of menstruation (Luris and Borenstein 1990). Symptoms include irritability, bloating (with swelling of the extremities), aggressiveness, heart pounding, fatigue, dizziness (with some fainting), and pain (especially headache and mastodynia <painful breast>). Dysmenorrhea is usually defined as exceptionally painful menstruation. It tends to begin just prior to the onset of or during menstruation. Sometimes it stops shortly after menstruation begins and sometimes it continues through the entire menstrual phase. Symptoms frequently include lower abdominal cramps, pain in the back and legs, mastodynia, headache, abdominal bloating, increased frequency of urination, nausea, and changes in bowel habits. Because the two problems can occur in the same person and because one stops just as the other begins, people who have both problems during the same month tend to be debilitated and in considerable discomfort for about three weeks out of four. The impact of either syndrome occurring alone is very significant for the work and quality of life of the victims. When they occur together, the problem can be overwhelming.

Prevalence of significant PMS is estimated to be fifty percent for young adult women (Hargrove and Abraham (1982) and between 30 and 40 percent among all women (Lurie and Borenstein 1990, Rossignol and Bonnlander, 1991). with some symptoms occurring among 40 (breast problems) to 80 (weight gain) percent (Boyle et al 1987). Logue and Moos's (1986) review of the literature indicates that two to ten percent of women have severe symptoms. Woods et al (1982) found that 17 percent of women reported severe pain with 30 percent reporting milder pain. Johnson et al (1988) reported that 3.2 percent of women surveyed reported severe symptoms although 87 percent reported at least some. It occurs among all types of women performing all types of work and there are no proven causes for it (Boyle et al 1987). Although clinics specializing in PMS treatment report almost exclusive attendance by Caucasians, community based surveys indicate the incidence and severity of the problem to be evenly distributed across racial groups (Stout et al 1986). About seven percent of Swedish women request treatment specifically for PMS (Hallmen (1986). No single treatment has been found to be effective for a large minority of sufferers (Friedman 1984).

Dysmenorrhea occurs in 30 to 75 percent of menstruating women (Davis 1988, Dawood 1985) with about 30 percent reporting severe symptoms (Pullon et al 1988). Stress and diet tend to be more highly correlated with severity of dysmenorrhea than other variables (Davis 1988). About six percent of women request treatment solely for dysmenorrhea (Ng et al 1992).

Gruber et al (1987) surveyed 293 young adult women and found that, in spite of the majority taking medications specifically marketed for menstrual pain, most missed a significant amount of required activities due to the pain. Dawood (1985) also found that a high degree of absenteeism was associated with dysmenorrhea. Surveys show that required daily activities including work were limited by dysmenorrhea among ten (Sundell et al 1990), 15 (Andersch and Milsom 1982), and 40 (Ng et al 1992) percent of young women.

We are not aware of any studies done on military women but Walter Reed Institute of Research did a study of 476 military wives which showed about the same findings as in the civilian community (Rosen et al 1990).

(3) Cognitive and other behavioral effects of PMS and dysmenorrhea: The results of studies are mixed. The best designed studies test subjects twice - once when their problem is active and once when it is not - and compare the subjects with matched controls. For example, Golub (1976) tested fifty 35 - 45 year old women who reported experiencing PMS. She found both anxiety and depression to be greater during episodes of PMS but not change in cognitive functioning. She did not have matched controls in her study. Keenan et al (1992) did have controls and tested both groups twice. They did find differences in cognitive functioning both between the controls and subjects with PMS as well as between phases of the menstrual cycle. The most important difference was the ability to learn new material. Mohan et al (1989) tested young adults (20 - 30 years of age) with severe PMS and found that their cognitive functioning decreased at the height of PMS. Rosen et al (1990) from the Walter Reed Army Institute of Research tested 476 military wives twice and found a high correlation between severity of PMS symptoms and cognitive depressive symptoms. Coleman et al (1988) found that about half of their 24 subjects with PMS showed cognitive differences while half did not. Kirstein et al (1980) found a high correlation between dysmenorrhea and concentration, pain, and negative affect for subjects tested several times and in comparisons between women with high and low dysmenorrhea scores.

(4) Treatment of PMS and dysmenorrhea with biofeedback:

(a) Overview of biofeedback: Biofeedback is a dynamic combination of learning processes and procedures in which the patient and the therapist receive information about the immediate status of a physiological parameter. Both can use this information to determine abnormalities in the parameter's level, reactivity, and way of functioning; and to correct any abnormalities identified. This information may be provided by (a) physiological recording instruments with displays designed to emphasize the changes and levels of interest to optimize the subject's ability to recognize the information of interest, and (b) the subject's own perceptions of the parameter of interest after special training is provided so that the subject can relatively accurately associate perceptions with actual levels of function. Although biofeedback devices are usually thought of as being mechanical or electrical, this need not be the case. For example, a mirror may be the optimal way to feed back information about motions of the knee during walking. The use of the mirror may be far better than an attempt to show a patient the same information through the use of many electronic goniometer and muscle tension sensors. The training subjects receive to sensitize them to the level at which the parameter of interest is functioning usually emphasizes increasing awareness of the parameter's level of functioning in the normal environment so the subject learns to recognize changes which lead to pain. A typical training regime for muscle tension awareness and control such as would be used for teaching patients who have PMS or dysmenorrhea would be (1) provision of about eight, half hour sessions in a clinic during which muscle tension levels of the trapezius muscles, masseter, or temporalis muscles would be displayed to the patient and (2) simultaneous home use of progressive muscle tension awareness and relaxation exercises similar to those developed by Jacobson (1970). Temperature training would be added for those patients who demonstrate symptoms related to altered peripheral blood flow patterns. The overall efficacy of biofeedback and the delineation of its techniques has been extensively reviewed elsewhere (Shellenberger 1994).

Any method capable of detecting the functioning of a bodily system and of displaying a change in the level as it occurs can be used to provide biofeedback. Physical therapists use themselves as biofeedback instruments when they use their fingers to ascertain how tense a muscle is and provide a stream of comments to the subject as changes in tension are noted. Specialized biofeedback instruments have been developed to increase the ability to detect those portions of the signal of interest and to give the provider the flexibility to tailor an optimal feedback display to each subject. Surface EMG feedback from the painful muscles is the most common type used for helping patients recognize and control their levels of muscle tension. Temperature feedback from the non-dominant hand's index finger is the most common type used for helping subjects learn to control peripheral blood flow patterns.

(b) Use of biofeedback to control PMS and dysmenorrhea: Virtually all of the articles identified are relatively small clinical studies and have short follow-up periods so little is known about the long term impact of biofeedback on work related deficits related to either PMS or

dysmenorrhea. Breckenridge et al (1983) gave 12 weekly EMG feedback sessions to eight young women with primary dysmenorrhea. They showed a significant decrease in severity of dysmenorrhea symptom scores on the Menstrual Symptom Questionnaire (Moos 1968). Balick et al (1982) did a similar study with the addition of temperature feedback given to nine dysmenorrheic women (aged 20 - 33) and found similar results upon six month follow-up. Bennink et al (1982) did a controlled study in which subjects who received only relaxation training or a no treatment control did not change while those receiving biofeedback did. Hart et al (1981) used a self-controlled design in which two month baseline and follow-up periods were compared for eleven subjects with primary dysmenorrhea. They used both GSR and EMG feedback and found a significant reduction in symptoms upon follow-up. Mathew et al (1979) treated twelve women with PMS with temperature biofeedback and found changes on the Menstrual Distress Questionnaire. Carson Henderson (personal communication, 1994) treated several dysmenorrheic women with a combination of biofeedback and relaxation training with considerable success and shared her techniques with members of this team.

2. BODY (METHODS):

a. Methods of procedure:

(1) Overview:

(a) As discussed in the summary, the study is evaluating the impact of severe PMS and dysmenorrhea on female soldier's performance of their normal duties and determining whether treatment with biofeedback alters this impact. Impact is assessed by having female soldiers from combat service and combat service support units requesting treatment for either PMS or dysmenorrhea fill out the Menstrual Distress Questionnaire (originally developed by Moos in 1968) as well as keep daily, month-long logs of their symptom activity, medication use, and limitations to their performance (both in relationship to their PMS and dysmenorrhea as well as to other problems). One month is the minimum length log acceptable because of the correlation between these problems, job performance, and the menstrual cycle. Each participant takes a one hour, automated cognitive performance test twice - once while their symptoms are at their height and once while at their minimum level. The subjects come to Madigan Army Medical Center once per week for six to eight consecutive weeks to participate in biofeedback training. They have already kept the log described above for one month prior to training and are keeping it again for an additional month at the end of training. They also take the cognitive tests again at the highest point of their cycles to determine the effect of treatment on cognitive functioning.

(b) Inclusion/exclusion criteria and examination: All subjects are essentially in good health other than their PMS or primary dysmenorrhea. Previous experience has proven that we can not utilize people with either complex medical problems or with severe behavioral complications in these high density recording studies. Each subject who received biofeedback was given a complete OB-GYN evaluation as well as a psychological screening evaluation including the Minnesota Multiphasic Personality Inventory II (MMPI-2) as detailed below.

PMS and Primary dysmenorrhea will be diagnosed from the Menstrual Distress Questionnaire using the criteria reviewed in the status section. They will be confirmed from the month long daily log described below. The investigators are not attempting to establish the psychiatric diagnosis of premenstrual dysphoric disorder (DSM IV) so those criteria for severely compromised patients do not apply to this study.

(c) Subjects: All of the subjects are female soldiers who requested treatment for PMS or dysmenorrhea at Ft. Lewis meeting the above criteria.

(2) Outcome measures:

Symptom and work impact log: Each subject filled in a short questionnaire (Moos 1968) on their symptoms and kept a four week log of symptom activity and the impact symptoms had on their work. Four weeks of information about symptoms including pain (intensity, duration, frequency) and impact on work performance is the minimum useful because of changes in performance due to the menstrual cycle and interrelationships between pain and that cycle. Each log covers two weeks of activity and fits on a single sheet of paper which can be

folded up and kept with the participant. Each participant was issued two logs. Each had a pre-addressed, stamped envelope stapled to it so that it could be mailed to the research team at the end of the second and fourth weeks of participation. A sample of the type of log to be used forms Figure One. They received an additional set of logs at the end of their treatment. Exact specifications for rating each parameter were explained to the subject and appear on the log. Pain was rated on a scale of zero to ten where zero is no pain and ten is so much pain that the subject could not imagine more pain if it had to be borne for one more second. Impact on work was rated on a scale of zero to ten where zero is no interference and ten is so much that the subject could not work at all.

(3) Biofeedback training: The biofeedback program consists of individual training in the standard muscle tension-awareness training procedures including muscle tension biofeedback and relaxation-pain avoidance procedures commonly used for treatment of PMS and dysmenorrhea as reviewed in the status section. This study utilized feedback of the surface EMG signal produced by the frontal (forehead) muscles from disposable Ag/AgCl sensors placed midway between the normal hairline and the eyebrows above each eye with a bandwidth of 8 - 1,000 Hz. The signal was amplified and then displayed on a light bar. Audio feedback in which pitch was proportional to strength of the signal was also provided. Following initial familiarization, those subjects who respond to stress with changes in their skin temperature received feedback of the temperature of their non-dominant index fingers using the same feedback signals as described above. Patients had one, hour-long, session per week for between six and eight weeks. Each patient was given a half hour, tape recorded "progressive" muscle tension awareness / relaxation exercise to use a minimum of three times per day. The ability of participants to alter their frontal muscle tension by 20 % of baseline and finger temperature by one degree Celsius upon demand was recorded so the amount of learning could be estimated.

(4) The cognitive test battery: Cognitive performance was assessed using a computer administered/scored tested called the Automated Neuropsychological Assessment Metrics evaluation (ANAM). It measures five cognitive domains: (a) attention/mental control, (b) memory, (c) reasoning/calculation, (d) spatial reasoning, and (e) reaction time. This automated battery required about one hour to take. It is designed for making test-retest comparisons over a short period of time and the formulae for adjusting for the learning curve are well worked out. Personality testing with be performed using the Personality Assessment Inventory. Patients were screened for depression with the Beck Depression Inventory.

b. Progress to date:

An incidence survey conducted as part of this study indicated that 55 % of female soldiers experienced symptoms of either PMS, dysmenorrhea, or a combination of both. From this group, 41 % of female soldiers reported significant symptoms of PMS, 17 % reported significant dysmenorrhea and 42 % reported a combination of both. Twenty subjects were given the Wonderlic Personnel Test, the Million Clinical Multiaxial Inventory and the Beck Depression Inventory as screening instruments. An ANAM evaluation was given to twenty-one subjects at the lowest symptom level and then at the highest symptom level to measure the relationship between cognitive functioning and the menstrual cycle. The tests showed that women's functioning is not effected by presence of either PMS or Dysmenorrhea. At the end of the treatment phase, five participants to date have taken a post ANAM test at their highest symptom level to determine the effects of treatment on cognitive functioning. Each participant filled out a month long log of their symptoms and their effect on work performance before and after six weeks of EMG and temperature biofeedback as well as muscle tension awareness and relaxation training. Eight participants have completed the treatment phase and 17 are still in progress. The results from the eight subjects who have completed the study showed that their symptoms decreased in intensity and frequency.

Figure One

TWO WEEK SYMPTOM AND WORK PERFORMANCE IMPACT LOG

Thank you very much for participating in this study on the impact of PMS (Premenstrual Syndrome), dysmenorrhea (painful menstruation), and headaches on your work performance. If you have questions about filling out this log or about the study, please call _____at _____.

Definitions:
Premenstrual syndrome (PMS) - is an overlapping group of uncomfortable to debilitating symptoms which tend to begin seven to ten days before menstruation and end a few hours after the onset of menstruation. **Symptoms** include irritability, bloating (with swelling of the extremities), aggressiveness, heart pounding, fatigue, dizziness (with some fainting), and pain (especially headaches and painful breasts).

Primary Dysmenorrhea - is an overlapping group of uncomfortable symptoms. It can also be debilitating and tends to begin just prior to the onset of or during menstruation. Sometimes it stops shortly after menstruation begins and sometimes continues through the entire menstrual phase. **Symptoms** frequently include lower abdominal cramps, pain in the back of the legs, painful breasts, headache, abdominal bloating, increased frequency of urination, nausea, and changes in bowel habits.

In order to determine the impact of PMS, dysmenorrhea, and headaches on your work performance, we need to know how much you are hurting, how long you hurt every day, the amount of impact these problems have on your work performance, and what you do about them. We need to know this information every day for a month so we can get a good idea of how your pain and other problems change with time.

To rate the combined intensity of your symptoms: We need to know a composite of how badly you are feeling (a combination of how severe of all of your symptoms combined are making you feel). Please use a scale of 0 (no problem with symptoms) through all of the numbers up to 10 (so severe that you couldn't bear it for one more second). For example, mild pain would be a 1 or 2 while a very severe pain might be an 8 or 9.

Impact of PMS, dysmenorrhea, and headaches: Work performance is effected in some way by these problems; for example, they may not be able to work as long or as effectively. You will be asked to rate the impact they have on your work performance when you are filling out the log. Please use the 0 - 10 rating scale (0 means no impact and 10 mean so much impact that you can't work at all and have to leave).

Please feel free to make additional comments anywhere you wish on this sheet.

Your Client Participation Identification Number: _____

Age: _____ (years)
MOS / SSI: _____
Work environment (e.g. spend most of day in a truck): _____

Type of work (e.g. spend most of day driving a truck): _____

Do you have sufficiently severe problems with either PMS, dysmenorrhea, or headaches for them to interfere with your life?
yes ____ no ____

If yes, rate the severity of impact that these problems have on your work performance. Use a scale of 0-10. For example, mild impact would be a 1 or 2 while a very severe impact might be an 8 or 9. _____

Which give you problems: PMS _____ dysmenorrhea ____
both PMS/dysmenorrhea ____ headaches _____

For how many years have you had them?: PMS _____ dysmenorrhea ____
both PMS/dysmenorrhea ____ headaches _____

What treatments (medications) have you tried for them? In the table, write in the type of medication and for which symptom: (e.g. aspirin/headache)

Treatment	Symptom	Treatment	Symptom
1		4.	
2.		5	
3.		6.	

List the two most important medicines you take for your PMS, dysmenorrhea, or headaches:

Drug Name	Dosage of drug per pill (mg)	Used for which symptom: PMS, dysmenorrhea, or headache
1		
2		

Remember, this is a two week log! Please make an entry every day.

Number of Pregnancies: _____

Type of contraceptives used: _____

Date your last period started: Month ____ Day ___ Year ___

Date This Log Started: Month ____ Day ___ Year ___

Please fill this log out every day for two weeks. Use the following key to fill in the symptom boxes: PMS=P, dysmenorrhea=D. For example: in the box titled "Worst pain", if you had PMS, you would put a P under the first numbered day. Next to the P, you would enter the number that best describes your pain (e.g. 2 for mild pain). The box under the first numbered day would then look like this: P

D
2

Pain Scale: 0-10 (0 no pain, 10 severe, can't bear another second)
Impact Scale: 0-10 (0 no impact, 10 - can't work, need to leave)

Day Number	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Worst Pain level for the day (Circle either P for PMS or D for dysmenorrhea and rate your pain using the pain scale)	P D	P D	P D	P D	P D	P D	P D	P D	P D	P D	P D	P D	P D	P D
Average Pain level for the day (Circle either P for PMS or D for dysmenorrhea and rate your pain using the pain scale)	P D	P D	P D	P D	P D	P D	P D	P D	P D	P D	P D	P D	P D	P D
Least Pain level for the day (Circle either P for PMS or D for dysmenorrhea and rate your pain using the pain scale)	P D	P D	P D	P D	P D	P D	P D	P D	P D	P D	P D	P D	P D	P D
Number hours of symptoms														
Awakened by symptoms (Y/N)														
Average impact on work (0-10)														
Number hours of work effected														
Number hours of work lost due to symptoms														
Took Medication? (Y/N)														
If Y, which ones? Number from front of log														
Number of pills taken														
Headache ? (Y/N)														
Rate headache (0-10)														
Number of work hours effected due to headache														
Number of hours of work lost due to headache														

When completed with this log, please mail it back to us in the attached, pre-stamped envelope. Thank you .

3. DISCUSSION AND CONCLUSIONS: This study is progressing at about half the rate anticipated when it began because active duty women simply do not have time to come to a clinic nine times in two months to participate in a study - especially when three of the times are basically to take tests.

If the remaining subjects show similar amounts of improvement to that shown by the completed subjects, it is very likely that the intervention will be shown to be effective with this population. However, it is not likely to be widely utilized by the military unless a way can be found to get the treatment to the soldiers in their work environments. Funding for a follow-on study to test this idea was turned down.

4. PRESENTATION: This work was presented at the annual meeting of the Association for Applied Psychophysiology held in Albuquerque during March of 1996. An abstract of the presentation will appear in the journal Biofeedback and Self-Regulation later this year.

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